

**Notice of Allowability**

Application No.

10/020,596

Applicant(s)

BECKER, MICHAEL M.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to interview of 17 January 2008.
2. ☒ The allowed claim(s) is/are 98-106.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 17 January 2008
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Charles B. Cappellari on 17 January 2008.

The application has been amended as follows:

Cancel claims 1, 3-5, 8-13, 16, 17, 19, 20, 28-32, 34, 36, and 61-97.

Add the following claims:

98. (New) In a homogenous assay method for detecting in a sample a hybrid formed between a labeled polynucleotide probe and a target polynucleotide in the presence of a polycationic polymer provided to the sample in an amount sufficient to increase the rate at which the hybrid is formed, the improvement comprising providing to the sample a dissociating reagent in an amount sufficient to dissociate the polycationic polymer from the hybrid after the polynucleotide probe and the target polynucleotide have had sufficient time to associate in the sample, and detecting the hybrid in the presence of unhybridized probe after the dissociating reagent has been provided to the sample.

99. (New) The method of claim 98, wherein the probe polynucleotide and the polycationic polymer are in solution during the formation of the hybrid.

100. (New) The method of claim 98, wherein the polycationic polymer is provided to the sample before the probe polynucleotide.

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101. (New) The method of claim 98, wherein the probe polynucleotide and the polycationic polymer are independently provided to the sample.

102. (New) The method of claim 98, wherein the polycationic polymer is a homopolymer.

103. (New) The method of claim 98, wherein the dissociating reagent is at least one of a polyanion and an anionic detergent.

104. (New) The method of claim 103, wherein the dissociating reagent is an anionic detergent.

105. (New) The method of claim 104, wherein the anionic detergent is lithium lauryl sulfate.

106. (New) The method of claim 98, wherein the hybrid is in solution during the detecting step.

2. The following is an examiner's statement of reasons for allowance: Claims 98-106 are allowable over the teachings of WO 91/08480 (Pontius), the closest prior art of record.

3. Pontius discloses the use of a secondary binding pair in combination with a primary binding pair (complementary nucleic acids; e.g., target and probe). Pontius, abstract and page 3, teaches that by use of the secondary binding pair, the hybridization reaction is accelerated from 10 to 100 times. Pontius, page 3, penultimate paragraph, teach that one member of the secondary binding pair can be a polycation. Pontius teaches numerous embodiments where both members of the secondary binding pair are coupled to the individual members of the primary binding pair; and at page 20, last paragraph, Pontius teaches that at least one of the members of the secondary

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binding pair must be "bound to a primary binding member at most times." Pontius has not been found to disclose the step-wise addition of the members of the secondary binding pair, much less the addition of a second member of the secondary binding pair after the primary binding pair has had time to hybridize to one another. Accordingly, the prior art does not teach or reasonably suggest the claimed invention.

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

6. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/  
Primary Examiner  
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BLS